AMENDMENT UNDER 37 C.F.R. § 1.116 Attorney Docket No.: Q86429

Application No.: 10/528,829

REMARKS

Upon entry of this Amendment, claims 51, 53, 71, 75 and 77 will be all the claims pending in this application. Claims 51, 53 and 75 are amended. Claims 52, 70, 72-74 and 76 are cancelled. By the amendments, features of previous claims 52, 70, 72-74 and 76 have been incorporated into the currently amended claims. The claims also now specify that the particles comprise a core which is formed of the polymer. Support for this feature can be found in the specification at page 18, lines 1 to 2. In remaining consistent with the description, the claims also specify that the polymer is water-insoluble and water-absorbing.

Applicants submit that the addition of the newly claimed feature does not raise new issues since it specifically addresses the Examiner's rejections. Applicants are combining features of dependent claims which were not previously combined. Applicants submit that this Amendment places the claims in condition for allowance.

Entry is respectfully requested.

The Claims are Patentable Under 35 U.S.C. § 103

The rejection of Claims 51 and 70-78 under 35 U.S.C. § 103(a) as being unpatentable over JP 11-322948 (JP '948) has been maintained.

The rejection of Claims 52-53 under 35 U.S.C. § 103(a) as being unpatentable over JP 11-322948 (JP '948) in view of WO 010303666 (WO '666) in further view of Ishihara et al (Polymer Preprints, 2001) has been maintained.

Claim 51 is newly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 6,416,740 ('740).

The Examiner takes the position that '740 discloses the features of claim 51, except for particle diameters in the range of 150 microns to 3000 microns. The reason for the rejection is

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that it would allegedly have been obvious to optimize the particle diameter taught by '740 in order to find the claimed range.

Applicants respectfully traverse the rejections. Claims 51, 53 and 75 are amended. Claims 52, 70, 72-74 and 76 are cancelled.

Applicants maintain and incorporate herein the arguments previously submitted in addressing '740, which relates to gas filled visicles. It is the Applicants' position that the present invention is distinct from, and non-obvious over, such disclosures. A skilled artisan would not have understood the term "particles of a polymer matrix into which is absorbed aqueous liquid," as is used in claim 51, to encompass gas filled microspheres. However, in order to advance prosecution of this Application, Applicants have amended the claims to more clearly require that the particles have a core comprising polymer.

The polymer is water insoluble and water absorbing, and the particles have aqueous liquid absorbed into them, i.e., into the water absorbing polymer matrix. It is further specified that the water content of the particles is at least 30%, as recited in previous claim 76. Applicants believe that, by these amendments, rejections based on '740 must be withdrawn.

JP '948 teaches small particle sizes. Such particles are clearly for systemic (i.e., into the blood circulation system) administration, perhaps as carriers for drugs. However, it would not have been obvious to a person skilled in the art to use sizes within the range required by claim 51, since such sizes would not be suitable for delivering drugs into blood circulation.

Rather, they would embolize peripheral blood vessels and be highly dangerous to administer. Although JP '948 suggests larger particle sizes, the working examples involve small particles in the range 100 to 170 nanometers; sizes above 1000 nanometers are clearly not preferred. Since, in JP '948, the objective is to form biodegradable particles, it is perhaps

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possible to avoid problems of embolizing peripheral blood vessels since the polymers may be selected so as to be biodegradable in a short period of time, whereby the peripheral embolisation would only be temporary. It thus appears that a person skilled in the art would only be able to use the larger particle sizes suggested by JP '948 (i.e., 1-100 μ m) under very rare circumstances, and would instead have an extremely strong preference for the smaller particle sizes (i.e., below 1 μ m). A skilled artisan would have been lead away from using even larger particle sizes than the upper limit of 100 μ m. Thus, Applicants traverse the Examiner's position that a skilled artisan would have been lead to explore larger particle diameters.

Applicants have amended claim 51 to specify that an embolus is intentionally formed. Furthermore, the polymer matrix must be substantially non-biodegradable. Since both of these features are to be avoided in JP '948, Applicants believe that the obviousness rejections based on JP '948 must be withdrawn.

It is Applicants' position that a person skilled in the art would read JP '948 as intentionally avoiding such a result. WO '666 describes the *in situ* formation of an embolic material. This is a totally different type of system for embolizing than that to which the present invention is directed, namely, the administration of pre-formed particles of water swollen polymer, which is administered in a method of embolizing. Even if the teachings of the art cited were combined, the method of the present invention would not have been achieved.

In view of the foregoing, none of the pending claims would have been obvious over any of the references cited, alone or in combination.

Withdrawal of the rejections are earnestly solicited.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

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Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

SUGHRUE MION, PLLC Telephone: (202) 293-7060

Facsimile: (202) 293-7860

washington office 23373 customer number

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